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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte EDWIN SOUTHERN

Appeal 2009-010829
Application 10/772,467
Technology Center 1600

Oral Hearing Held: May 13, 2010

Before LORA M. GREEN, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, Administrative Patent Judges.

ON BEHALF OF THE APPELLANT:

WARREN M. CHEEK, ESQ.
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The above-entitled matter came on for hearing on Thursday, May 13, 2010, commencing at 9:59 a.m., at the U.S. Board of Patent Appeals and Interferences, Madison Building, East Wing, 600 Dulany Street, 9th Floor, Alexandria, Virginia, before Jon Hundley, Notary Public.

THE USHER: Calendar No. 58, Appeal Number 2009-010829. Mr. Cheek.

JUDGE GREEN: Thank you. Good morning, Mr. Cheek.

MR. CHEEK: Good morning.

JUDGE GREEN: If you have a card for the transcriptionist, that would be greatly appreciated.

MR. CHEEK: I do.

JUDGE GREEN: We are familiar with the facts of your case. You have 20 minutes whenever you would like to begin.

MR. CHEEK: Thank you very much. Good morning. My name is Warren Cheek. I'm with the firm of Wenderoth, Lind & Ponack, and I'm here representing the Appellant, Edwin Southern, in this Appeal, Serial No. 10/772,467.

As a preliminary matter, I'd just like to mention that in the Appellant's Brief, it's noted there are two related Patents of the inventor, USP 5,700,637 and USP 6,054,270. Both of these Patents are mentioned in the brief as being involved in a re-examination proceeding at the time of filing the Brief.

Since that time, the re-examination proceedings have been concluded, and in both Patents, re-examination certificates have issued with numerous claims. There were some amendments to the claims.

Turning to this Appeal, there is a single ground of rejection of the Claims under 35 U.S.C. 103. The Claims on appeal and under rejection are Claims 17-26 and 86-87. These Claims are rejected as unpatentable over the teachings of Stavrianopoulos, USP 4,994,373, and Matkovich, USP 4,828,386.

Before getting into the details of the rejection, I'd like to mention there are four groupings of claims that are separately argued in the Brief, so the Appellant would respectfully request the Board's consideration of each grouping of claims with respect to the rejection.

Briefly, for your convenience, I'll summarize the groupings. Group one is Claims 17-22 and 26-27. Claim 17 is the main independent claim, the broadest claim, and is directed to an apparatus for analyzing the polynucleotide using oligonucleotides attached to a support. The details of Claim 17 will be addressed in just a minute.

Claims 18-22 and 26-27 are dependent upon Claim 17 and are not separately argued.

Group two is Claims 23 and 86. Claim 23 is dependent upon Claim 17 and requires that the oligonucleotides, which are attached to the support, are covalently attached. Claim 86 is an independent claim and is essentially the combination of Claims 17 and 23.

Group three is Claims 24 and 87. Claim 24 depends on Claim 17 and requires that the oligonucleotides be attached to the support by a terminal oligonucleotide. Claim 87 is dependent upon 86 and recites the same limitation.

Lastly, group four is Claim 25. This is dependent upon Claim 17 and requires the oligonucleotide to be synthesized in situ.

Turning now to the main independent Claim 17, I'd just like to briefly summarize its features. It's a short claim. Apparatus for analyzing a polynucleotide. The first requirement being the apparatus comprise a support having an impermeable surface with porous material attached to the impermeable surface.

The second requirement for simplicity I will describe as the next recited feature of Claim 17, an array of oligonucleotides with predetermined sequences attached to the porous material.

The third requirement follows the second requirement of the claim. The array must comprise at least two defined cells and the sequence of the oligonucleotides in a first cell is different from the sequence of oligonucleotides in a second cell.

Lastly, in the claim as it's recited, the fourth requirement being the oligonucleotides are shorter than the polynucleotide to be analyzed.

Any questions up to this point? This is pretty basic.

JUDGE GREEN: We understand all that.

MR. CHEEK: Thank you. Turning to the rejection, it is first respectfully submitted that the rejection is improper as being based upon non-analogous art. The present invention is directed to an apparatus for analyzing a polynucleotide, similarly, the primary reference to Stavrianopoulos is also directed to an apparatus for analyzing a polynucleotide.

However, the secondary reference relied upon by the Examiner, Matkovich, is directed to an entirely different apparatus, which is directed to increasing the reliability and sensitivity of an antibody microtiter well.

The concept of the secondary reference as explained in the reference is to try to improve the reliability and sensitivity of an antibody microtiter well. The invention --

JUDGE FREDMAN: Basically what the Examiner is saying is these are analogous because these are both assays which are using coupling and basically Matkovich simply shows that covalent coupling is a way you can attach the agent to the array. I think that is something we want to focus on.

My question on predetermined, which I think is the central question, to me, when you say "predetermined," I think of that as a product by process limitation. In other words, it doesn't structurally impact the array itself; right?

If there are two different arrays, I take an array and I predetermine what I put on it and I have molecules A, B and C, and you have an array and you put on A, B and C, but you didn't decide what they were in advance, that's just what's on your array, we end up with arrays that are potentially identical arrays, simply the difference being I decided what to put on them first and you didn't. Can you explain why that isn't the case?

MR. CHEEK: That isn't the case, and it is respectfully submitted it's not a product by process limitation because the meaning of the term "predetermined," which originates from Examiner Artin Marschel, who originally allowed it, and at that time, we were contemplating the term

"known," and there is a long history, but it was agreed that "predetermined" was a very accurate way of describing that each and every oligonucleotide, the sequence of each and every oligonucleotide on the array is known, and that's not a product by process limitation. You could make it into one.

JUDGE FREDMAN: How does that change the array?

MR. CHEEK: The array -- the main difference between our apparatus and Stavrianopoulos' is in Stavrianopoulos, the sequences are unknown that are immobilized and the known sequences -- we have totally known sequences.

JUDGE FREDMAN: I understand the differences. It's not a question of understanding the invention. It's a question of from a structural standpoint, how does the structure differ based on what the Inventor knows?

MR. CHEEK: The structure differs because there are -- in most of the embodiments, there are thousands of cells of different oligonucleotides.

JUDGE GREEN: That is not what you're claiming. Claim 17 only has two different -- that's what we have to focus on. If you have two oligo's immobilized and in one case, like Judge Fredman says, one person knows the structure or the sequence of the oligo's and in the second case, the person using it does not, how does the structure itself differ in those two particular cases, just because one person knows the sequence and the second person doesn't?

Suppose someone was using the array, the second person picks it up but doesn't know what the sequences are, does that mean it no longer falls within your claim?

MR. CHEEK: Yes.

JUDGE GREEN: The same piece of equipment. The first person knows what the sequences are, the second person doesn't because they are just picking it up and putting it away, that person would not be infringing because he doesn't know what the sequences are.

JUDGE FREDMAN: In a product claim.

JUDGE GREEN: In a product claim.

MR. CHEEK: I could also say that's not part of the rejection.

JUDGE GREEN: No, but we're just trying to figure out the scope of your claim.

MR. CHEEK: The scope of the claim is that the apparatus has a support and the entire sequence of every oligonucleotide is known on the support such that when something binds to that oligonucleotide, you can look it up and know exactly what the sequence is of the probe that binds to it.

JUDGE GREEN: That relates more to a method of using than to the apparatus itself.

MR. CHEEK: We would respectfully disagree. This is a central issue but it's not the only issue as to why the rejection should be overturned.

The fourth limitation of the claim is that the oligonucleotides are shorter than the polynucleotide. There is absolutely no mention in the Rejection or in the Examiner's Answer as to why the prior art teaches or suggests that feature.

JUDGE FREDMAN: Again, that is really a process limitation because the polynucleotides coming in are entirely dependent on what the experimenter chooses. That doesn't change the array. It depends on what is being done to the array. You're trying to import a limitation of a method of use in which the polynucleotides being used are longer. That is really not a product limitation; right?

I think there are ways this could be written, although I'm not entirely sure or I would suggest them, to incorporate these as structural, but I don't know that this claim captures that.

I would actually ask if we could jump for one second, you may want to say more about 17, but I'd like to go to 25 for a second.

MR. CHEEK: Yes, sir.

JUDGE FREDMAN: 25 says in situ. Again, that is a method of limitation, but in the context here for 25, it seems to me the implication of in situ is essentially it doesn't depend on 24, it depends on 17, but I'm unaware at the time of filing any way of doing in situ synthesis other than by a terminal oligonucleotide covalent attached to the support.

I think that is what your spec shows. Is there any other way? In other words, when you say "in situ synthesis," can that mean something other than covalent attached by a terminal oligonucleotide or is that really required?

MR. CHEEK: I'm not sure. I could contact the inventor. I'm sorry, I don't know.

JUDGE GREEN: There is nothing in your specification that would imply it means anything differently?

MR. CHEEK: No, not to my knowledge.

JUDGE FREDMAN: In light of your spec, we could read it as requiring the covalent attachment potentially.

MR. CHEEK: Potentially.

JUDGE FREDMAN: That is a reasonable way of reading it.

MR. CHEEK: Yes, I'd have to agree with that, at least as a potential interpretation.

JUDGE FREDMAN: Right.

MR. CHEEK: Another point that I'd like to address is the third requirement of the claim that the array comprises at least two defined cells, the sequence of the oligonucleotides in the first cell is different from the sequence of the oligonucleotides of the second cell.

The Examiner has two arguments for this, neither of which it is respectfully submitted are reasonable. One argument is that the primary reference, Stavrianopoulos, teaches in the examples of making constructs with different DAS, such as lambda or adenovirus. However, these constructs are taught in different examples.

There is absolutely no suggestion in the reference to combined different DNA samples into a single construct, and even if you did, according to this hypothetical, the Stavrianopoulos assay wouldn't work because you then have two analytes of unknown sequences on the support and you wouldn't know what it was binding to.

It simply wouldn't work. On this single basis alone, the rejection is untenable.

JUDGE PRATS: I'm looking at Column 8, I think that is the portion the Examiner cited, Column 8, line 41. "For example, glass plates provided with an array of depressions or wells would have samples of the various analytes deposited therein, the single stranded analytes being fixed to the surfaces of the wells."

Doesn't that kind of suggest you could have different samples on each of the wells? I think that's what the Examiner is trying to say. I understand your point about the different examples. He picks lambda and adenovirus from one of the other examples.

It seems that passage right there at Column 8 --

MR. CHEEK: The Examiner has latched onto that one word, "various," and it's our position that the Examiner's interpretation of the sentence and that term "various" is unreasonable. Only in pure hindsight, if you read the entire specification of Stavrianopoulos, it solely talks about a single analyte on the surface, and I would just mention that as you can appreciate it, if you have two unknown analytes on a surface, you don't know which the known sequence probe that is in solution phase is going to bind to.

What is a more reasonable explanation --

JUDGE FREDMAN: Stavrianopoulos teaches you can use multiple or different labels. You could just label two different things with -- two different probes with two different labels.

MR. CHEEK: He doesn't teach putting two -- this is the only word in the specification that you could construe as the Examiner has to mean different sequences on the surface.

It's my suggestion that the real meaning of this and still, it's not entirely known for sure, but the sentence begins "Glass plates provided with an array of depressions or wells which would have samples of various analytes."

My interpretation is that there are different plates with different samples. Nevertheless, there is only the same sample on each plate. I think that is a more reasonable interpretation of that sentence.

To rely upon that single word "various" in the entire specification to mean something totally different than what the remainder of the specification does, it just seems to be unreasonable to us.

JUDGE FREDMAN: We also talk about how one ordinary in the skill would be able to understand these things. The skill level at the time of invention, do we analyze one thing at one time or do we analyze multiple things.

MR. CHEEK: At the time of this invention, back in 1988, this was cutting edge. There was no such --

JUDGE FREDMAN: When is your filing date?

MR. CHEEK: It relies upon a British application in 1988.

JUDGE FREDMAN: I've actually looked at these before in my career.

Even in 1988 and before that, there were arrays, there were things, for example --

MR. CHEEK: But not on such a support as this.

JUDGE FREDMAN: I think you even had them on glass. The real difference here is these are really microarrays, you don't quite capture

that because you don't put in the limitation of dots per inch, which often will distinguish these.

MR. CHEEK: That is deep in the claim.

JUDGE FREDMAN: That's the real difference here. It's not captured by the claim, by the independent claim.

MR. CHEEK: I know there are just a few minutes left. I just would like to briefly touch on the other groups of claims, which I'm not sure we talked about, Claims 23 and 86 requires an oligonucleotide to be attached covalently. Stavrianopoulos clearly teaches only non-covalent ionic attachment. I think we have established that in the record.

The secondary reference mentions covalent attachment but that's only in a generic type of way, and due to the non-analogous nature of the secondary reference, it's our suggestion that one skilled in the art would not have been motivated to modify the non-covalent ionic attachment of the primary reference with this type of covalent attachment.

On this issue of non-analogous art also, the Examiner has broadly defined this as a field of attachment of macromolecules, but it's our submission that the field that one skilled in the art making polynucleotide arrays would not really look to this.

The field in our position is much narrower than that, and why would one skilled in the art look to a reference in the antibody microtiter well art, which is trying to improve sensitivity of microtiter wells, in designing a polynucleotide array for detecting single based differences in analyte nucleotides.

JUDGE PRATS: If I may, doesn't the Examiner actually also point to Column 6, I understand the focus of Matkovich, it actually seems to be antibodies, but there is this blurb in Column 6, line 60, saying you can also use it for a bunch of other things including -- the last item is nucleic acids.

Does that get the Examiner outside of the analogous argument?

MR. CHEEK: We don't think so. Just because it's a blurb that mentions, as you say, and we agree, it's a blurb that mentions a word. It doesn't really change the interest of one skilled in the art in terms of trying to make a polynucleotide array. The art is different and probably one skilled in the art wouldn't be looking at this antibody microtiter well to see any vague general teachings such as that.

Lastly, Claims 24 and 87, these require attachment of the oligonucleotides by a terminal oligonucleotide. The Examiner simply says well, this is encompassed by attachment taught by the references.

JUDGE FREDMAN: There is no specific teaching of that; right?

MR. CHEEK: No, definitely not. In fact, the Examiner agrees on that. It's in the Answer. She says it's encompassed. We would submit that being encompassed is not the same thing as being a teaching or suggestion, which would motivate somebody to make something according to our claim.

From the standpoint of what the art was at the time, the art of attaching nucleic acids to porous supports at the time involved usually internal adenovirus type attachments.

At the time of the invention, it really was not something that would be automatically envisioned, much less the references don't enable one to prepare this embodiment.

It is respectfully submitted that at least Claims 24 and 87 are clearly not obvious over the cited references and for all the other reasons, the remainder of the claims as well.

JUDGE GREEN: I think we understand your argument. Do you have any further questions?

(No response.)

JUDGE GREEN: Thank you.

MR. CHEEK: We sincerely appreciate your consideration; good questions.

JUDGE FREDMAN: Thank you.

Whereupon, at 10:22 a.m., the proceedings were concluded.